SCIENTIFIC FRAMEWORK OF HOMEOPATHY Evidence Based Homeopathy

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SUMMARY:

This booklet is aimed at considering all important aspects of the scientific framework of Homeopathic practice including ethical questions, evaluation of daily practice, looking at the level of scientific evidence of each of these aspects in an objective way. The conclusions are clear, homeopathy has to stay in the framework of medical practice and it is even a necessity for public health. Of course more research is always necessary.

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CHAPTER I

Introduction

The aim of this booklet is the study of the current framework of the practice of homeopathy in the world. The scientific adequacy will be considered regarding the level of evidence currently available for each considered aspect.

What is a level of evidence?

Level of evidence:

I = the existence of meta-analyses and/or systematic positive « reviews » of the literature.

IIa = controlled multiplied experiments, randomised positive.

IIb = some controlled experiments, randomised positive.

IIIa = study with multiple cohorts positive.

IIIb = study with some cohorts positive.

IV = opinion of experts (clinical and daily cases)

The use of homeopathic medicines is widely spread throughout the world population. In Europe, these medicines are submitted to a registration procedure (1) which guarantees an optimal pharmaceutical quality and safety for users.

A potential risk exists only when these medicines are used without foregoing medical diagnosis. To minimize this risk it is essential to keep homeopathy within the framework of medical practice.

In several countries, a law on patients' rights has come into force. It means that the patients have the right to choose or to refuse a proposed treatment. But medical doctors cannot inform the patient correctly if they do not know all possible medical approaches and as such an ethical dilemma is created.

It is essential for public health to formulate concrete answers to all these questions. This booklet is also aimed to help at the formulation of pragmatic solutions to these problems.

(1) European Directives 2001/83/EC (ex 92/74/EC), 2004/27/EC & 2001/82/EC (ex 92/74/EC), 2004/81/EC.

CHAPTER II

General framework and ethical point of view (2).

First part

A. The place of the non-conventional medicine in our public health system.

The **World** Health Organisation (<u>WHO</u>) concludes in a report of May 2005, concerning politics about traditional medicine in different countries (3), that traditional medicine (TM), all over the world, maintains its popularity. In addition, during the last 10 years the use of CAM (Complementary and Alternative Medicine) has increased in several countries. The safety of the use of these products, their quality control and their evaluation in term of efficacy, are priorities for the political authorities as well as for the population.

The WHO questioned their 191 members. 141 countries (74%) answered.

32% of these countries have developed a policy of health including TM/CAM.

56% stated that a policy concerning TM/CAM is in "construction".

Only 5 countries developed this regularisation already before 1990.

28% have an adapted national program specific to TM/CAM

58% have put in place a national committee responsible for TM/CAM. In most cases this committee is part of the Health Department. 43% of these countries have established a committee of experts for TM/CAM.

A problem of harmonisation exists between the different countries. Major difficulties are the absence of a standardized educational programme for TM/CAM and a lack of experts on this matter. Countries are asking the support and advice of the WHO. to develop a national policy concerning the regularisation of TM/CAM.

In *Europe* the report "Concerted Action for Complementary and Alternative Medicine (CAM) Assessment in the Cancer Field" (4) observed the same tendency concerning an increase in the use of CAM. This evolution goes on in different countries within different scientific frameworks.

⁽²⁾ Le Roux P, Van Wassenhoven M. Médecines non conventionnelles dans les institutions de soins? *Ethica Clinica 2006 n°42*.

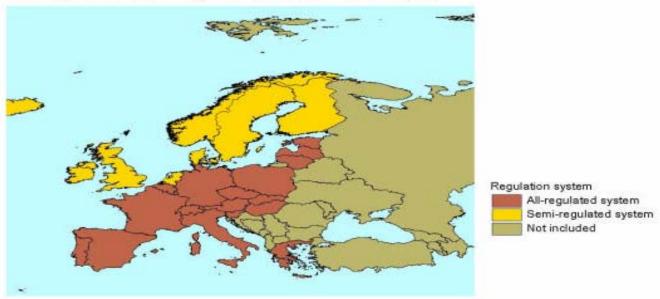
⁽³⁾ National policy on Traditional Medicine and Regulation of Herbal Medicines. Report of a WHO global survey. WHO 2005 Dr Xiaorui Zhang http://www.who.int ISBN 92 4 159323 7

⁽⁴⁾ How are European patients safeguarded when using complementary and alternative medicine? Juridictions, supervision and reimbursement status in the EEA area (Eu and EFTA) and Switzerland. CAM-CANCER project funded by the European Commission within the 5th Framework Programme "Quality of Life" 10-2005 http://cam-cancer.org

Diagram 1: Regulation in European countries (CAM-CANCER report).

	« fully controlled systems » n=19	« partial controlled systems » n=10			
Countries	Austria, Belgium, Cyprus, Czech Republic, Estonia, France, Germany, Greece, Hungary, Latvia, Lithuania, Luxembourg, Italy, Poland, Portugal Spain, Slovenia, Slovakia, Switzerland,	Denmark, Finland, Iceland, Liechtenstein, Irland, Malta, The Netherlands, Norway, Sweden, UK			
Who is allowed to treat?	Statutorily regulated individuals.	Statutorily regulated individuals.	Everybody		
Authorized	-"risky" medical procedures	-"risky" medical procedures			
Medical	-treating serious diseases	-treating serious diseases			
activities:	-safe medical procedures -preventive/prophylaxis	-safe medical procedures -preventive/prophylaxis	-safe medical procedures -preventive/prophylaxis		

Regulation systems in Europe



In 19 of the 29 European countries (Central – and South Europe) only the statutorily regulated individuals have the legal authorization to treat patients. In the 10 remaining countries (North – Europe) non-statutorily regulated individuals can offer care. In these countries several responsibilities stay in hands of medical doctors. The authorities control CAM practices by a "permit to practice", a licence, a protected title or voluntary registration. A supervising commission is installed in these countries. This commission determines which type of CAM can be considered as "sound professional practice" when delivered by statutorily regulated individuals. The practice by statutorily regulated individuals is strictly limited in some countries whereas in other countries these statutorily regulated individuals can have a free, unlimited practice.

"Plants" and homeopathic medicines authorized on the market are controlled by specific European directives and these directives are implemented in national legislation.

How can we protect patients from treatment inadequacy? The best way would be the recognition of CAM treatments in an adequate and legal way but is it better to limit the practice of CAM to accredited persons (Central and South Europe) versus not accredited persons (Northern Europe)? Is the efficacy and quality of the CAM sufficiently verified in order to consider its introduction in the healthcare systems?

Table 2: regulated CAM in different European countries.

X: year of legalisation unknown.

Y: new law in preparations.

Countries	Regulating CAM providers by law								License	CAM Register
	No Yes									
		Chiro-	Osteo-	Napra-	Homeo-	Acu-	Naturo	Phyto-		
		practics	pathy	pathy	Pathy	puncture	-pathy	therapy		
Austria	no									
Belgium		1999	1999		1999	1999				
Bulgaria					2005					
Cyprus		Х	y			у				
Czech Republic					2002					
Estonia	no									
France	no									
Denmark		1992								2004
Finland		1994	1993	1994						
France			2002							
Germany									1939	
Greece	no									
Hungary									1997	
Iceland		1990	2005							2005
Ireland	no									у
Italy		Х								
Latvia					X	X				
(physicians)										
Liechtenstein		1985								
Lithuania					Х					
(physicians)										
Luxembourg	no									
Malta		X	X			X				
The Netherlands	no									
Norway		1988								2004
Poland	no									
Portugal		2003	2003		2003	2003	2003	X		

Spain	no									
Slovakia	no									
Slovenia	no									
Sweden		1989		1994						у
Switzerland		X	X						X	
UK		1994	1993		1950	у		у		X
Number	11	13	8	2	7	4	1	1	3	4

Teaching of homeopathy and use in hospitals in 22 European countries (5)

Austria:

Officially recognized diploma as an additional qualification (medical doctor / veterinary doctor qualified in homeopathy). Postgraduate education. Optional **introduction course** on CAM during basic education at the universities of Vienna, Innsbruck and Graz. *In 7 hospitals homeopathic care is possible on consultation.*

Belgium:

Post-graduate **diploma** delivered by private schools. A National diploma exists delivered by the Homeopathic Faculty, grouping the different schools.

A compulsory optional **introduction course** at the University of Leuven (U.C.L.)

No official possibility for homeopathic care in hospitals but patient's rights include homeopathy as a possible patient choice in collaboration with the family medical doctor.

Bulgaria:

Postgraduate **diploma** in private schools recognized by the medical association. *No possibility of homeopathic care in hospitals.*

Czech Republic:

Postgraduate **diploma** in private schools.

No possibility of homeopathic care in hospitals.

Denmark:

Education in private schools open for everybody (no former medical education required) *No possibility of homeopathic care in hospitals.*

Finland:

Education in private schools open for everybody (no foregoing medical education required)

No possibility of homeopathic care in hospitals.

(5) ECH – Legal status of Homeopathy in Europe. Overview 2005 – updated 2007.

E.C.H. - info@homeopathyeurope.org - L.M.H.I.

France:

Officially recognized **diploma** as an additional qualification (medical doctor /veterinary doctor qualified in homeopathy). Post-graduate education at the universities in Aix-Marseille, Besançon, Lille, Paris-Bobigny, Bordeaux II, Limoges, Poitiers and Lyon. Private schools also exist

Optional **introduction course** of CAM during the basis education at some universities In 2 hospitals patients can come for a homeopathic consultation: Hôpital St. Jacques en Hôpital St. Luc Paris.

Germany:

Officially recognized **diploma** as an additional qualification (medical doctor /veterinary doctor qualified in homeopathy). Post-graduate education at the universities of Berlin, Düsseldorf, Hannover, Heidelberg and Freiburg.

Private schools also exist

Compulsory optional **introduction course** of CAM during the basic education at some universities

In 1 hospital patients can come for a homeopathic consultation: 'Charité' hospital in Berlin.

Greece:

Postgraduate **diploma** in private schools and some universities.

No possibility of homeopathic care in hospitals.

Hungary:

Postgraduate **diploma** in private schools recognized by the medical chamber.

No possibility for homeopathic care in hospitals.

Ireland .

Postgraduate **diploma** in private schools open for everybody (no foregoing medical education required).

No possibility for homeopathic care in hospitals.

Italy:

Officially recognized **diploma** as an additional qualification (medical doctor /veterinary doctor qualified in homeopathy). Post-graduate education at the University of Aquila. Private school exist also.

Optional **introduction course** of CAM during the basis education at some universities *No possibility for homeopathic care in hospitals.*

<u>Luxembourg:</u>

Postgraduate **diploma** in private schools.

No possibility for homeopathic care in hospitals.

Netherlands:

Postgraduate **diploma** in private schools.

Optional **introduction course** of CAM during the basis education at some universities *No possibility for homeopathic care in hospitals.*

Norway:

Education in private schools, open to everybody (no foregoing medical education required).

No possibility for homeopathic care in hospitals.

Poland:

Officially recognized **diploma** as an additional qualification (medical doctor /veterinary doctor qualified in homeopathy). Post-graduate education at 8 universities.

No possibility for homeopathic care in hospitals.

Portugal:

Postgraduate **diploma** in private schools.

No possibility for homeopathic care in hospitals.

Romania:

Officially recognized **diploma** as an additional qualification (medical doctor /veterinary doctor qualified in homeopathy). Post-graduate education at 8 universities.

Optional **introduction course** of CAM during the basis education at some private universities

No possibility for homeopathic care in hospitals.

Slovenia:

Postgraduate education at the private school of the Slovenian Homeopathic Society accreditated by ECH.

No possibility for homeopathic care in hospitals.

Spain:

Officially recognized **diploma** as an additional qualification (medical doctor /veterinary doctor qualified in homeopathy). Post-graduate education at the universities of Sevilla, Murcia and Barcelona.

Optional **introduction course** of CAM during the basis education at some universities *No possibility for homeopathic care in hospitals.*

Sweden:

Education in private schools open for everybody (no foregoing medical education required).

No possibility for homeopathic care in hospitals.

Switzerland:

Postgraduate **diploma** in private schools. At the university of Bern education in CAM is available.

Homeopathic care only in private hospitals.

Great - Britain:

Officially recognized **diploma** as an additional qualification (medical doctor /veterinary doctor qualified in homeopathy). The official recognized "Faculty of Homeopathy" delivers the diploma's. Postgraduate education in private schools open for everybody. Optional **introduction course** of CAM during the basis education at some universities In **5 hospitals** homeopathic consultations are possible: London, Liverpool, Bristol, Tunbridge Wells and Glasgow.

Homeopathy in intensive care and emergency services:

Recent publications show the benefit of homeopathy in hospitals but also in emergency services for patients in critical state (6a,b,c). The authors suggest the development of algorithms including homeopathy allowing quick and adequate reactions for these patients.

The place of CAM in the U.S.A.:

The Consortium of the Academic Health Centres (7) integrate CAM in **30 university medical centres**. As in Great-Britain the concept of "integrated" medicine predominates. All possible treatments must be offered to the patient. This attitude is based on the results of intensive scientific research on CAM Until now the results are very hopeful for homeopathy.

Summary of first part:

In the World, the use of homeopathy has increased in a lot of countries. In Europe, homeopathy, as other CAM, is already partly regulated. Homeopathy is integrated in 5 of the 22 countries. Medical students get familiar with CAM by an introduction course in 9 of the 22 countries. A postgraduate diploma in homeopathy is recognized in 18 of the 22 countries. Despite the interest there are still some queries outstanding before considering full integration in all countries. Part 2 will study the reasons for this reservation.

- (6a) Oberbaum M et al. (2005). Homeopathy in emergency medicine. Wiener Medizinische Wochenschrift, 155:491-7. // Frass M et al. (2005). Adjunctive homeopathic treatment in patients with severe sepsis: a randomized, double blind, placebo-controlled trial in a intensive care unit. Homeopathy, 94:75-80. // (6b) Frass M et al. (2005). Influence of potassium dichromate on tracheal secretions in critically ill patients.
- (6b) Frass M et al. (2005). Influence of potassium dichromate on tracheal secretions in critically ill patients. Chest, 127:936-41.
- (6c) Marques Arpa A (LMHI 2008). Arnica in sepsis: Clinical cases at the Intensive Care Unit with Complementary Homeopathic Treatment.
- (7) http://www.imconsortium.org

Second part

<u>Arguments in relation to the reservation against CAM in general and homeopathy in particular.</u>

We know that in some European countries integration of homeopathy in the health service, even at University hospitals, is already accomplished. Nevertheless, two groups resist this integration.

On one side, the pharmaceutical industry, with its enormous financial power: they do not like the development of "other" medical medicines that could be an alternative for their market. This resistance is not really structured but competition is always a problem and if there is some opportunity to limit the action field of the "others" they will not hesitate to use it.

On the other side, are the "rationalists". These groups are not so numerous but very well organised and very influential on the mass media. They have at their disposal big financial means and an efficient network of relations. One single argument is sufficient to condemn everything they do not accept: "it is simply impossible that something would exist out of their rational world".

Facts are rejected, a priori, because they must be false. "Somewhere there must be an error". This "rational world" is based on and limited to the molecular paradigm which is part of molecular biology. Outside this scientific paradigm nothing exists. However, other intercellular communication means do exist. Biophotons (8) and biophonons (9) have been identified; they are activated by the communications between cells and molecules. Together with the molecular print in a solvent (10) these facts are all irrefutable. Even the effects of hormones cannot be explained only by the molecular theory because the amount of molecules is insufficient to explain the amount of activated cells receptors; this is the so called "amplification" phenomenon. Without attached molecules on the cell receptors, we can observe a reinforcement of the hormonal effect.

⁽⁸⁾ Popp: Electromagnetic Bio-information" edited by Urban and Schwarzenberg in 1989

⁽⁹⁾ Frohlich : existence of coherent longitudinal electromagnetic waves of low energy ($hV \le \kappa T$) in living organisms.

⁽¹⁰⁾ Rey L.R., Thermoluminescence of ultra-high dilutions of lithium chloride and sodium chloride, Physica A, 2003, 323: 67-74.// Rey L.R., Glimpses into the physical behaviour of ultra-high dilutions, LMHI 2008.

The major reason for refusal to authorize any scientific research in the field of CAM. is only due to the theoretical reticence of an influential group of people. They find that research is not necessary. Possible cures are all due to the placebo effect! Of course they forget the results achieved on animals and children. As an example of this obstruction to research, we can consider a publication in "The Lancet" (11), in fact a scientific fraud (12), and this is sufficient to justify real research into homeopathy. The conclusions of the publication were written before inventing a new mathematic model for literature analysis that could confirm these conclusions. Unfortunately, the strict application of this new method came to a conclusion they did not desire,, namely homeopathy is efficient in certain areas. The authors preferred to avoid these results and to quote only some negative results in accordance with the "a priori" decided conclusions. Only by redoing this statistical exercise, was it possible to confirm the fraud. The experts of "The Lancet" were only interested in a negative result and in the impact such publication could have in the mass media.

It is only a war between two different paradigms. The dominant paradigm must explain everything and if something cannot be explained by this dominant paradigm, it will be considered as false. However, a new paradigm exists and can explain all facts; it is <u>the paradigm of information</u>. It does not "eliminate" the <u>molecular paradigm</u>, it is an additional paradigm that can explain facts that the molecular paradigm does not explain.

The last reason for rejection is that common medical doctors, especially specialists, are not interested in other medical approaches. They know very well what they are doing every day; they are satisfied with the results obtained in a majority of their patients and do not need something else so far of their daily practice. They are only interested in more research and information about improvement of their actual practice. If some patients are not ameliorated by, or do not tolerate the proposed treatment, they are classified as "difficult", "untreatable" patients. The therapy will not be questioned and research on other approaches will not be considered. They are not "against" homeopathy but why would they encourage better studies on this medical approach?

⁽¹¹⁾Shang A, Huwiler-Müntener K, Nartey L, Jüni P, Dörig S, Sterne JAC, Egger M. Are the clinical effects of homeopathy placebo effects? Comparative study of placebo-controlled trials of homeopathy and allopathy. Lancet 2005;366:726-32

⁽¹²⁾ECH: Epibooklet 2006. www.homeopathyeurope.org

Third part

Ethical aspects

The Position of Ethics.

Two fundamental rights must be taken into account: <u>the therapeutic freedom for therapists</u> and <u>the freedom of choice of therapy for the patient.</u>

1. the bio-ethic of the 21the century and her sources:

It is good to mention some existing important ethical lines and their applications in the field of alternative medicine. If we consider the actual medical ethic, one can observe that there is a tendency to go further than the oath of Hippocrates, just because the ethic is taking into account technical and human complexity. So medical ethics is in permanent mutation and permanently questioned.

a. Appearance of the medical techno-science.

In the context of the medical technology, especially in the fields of research connected with human life, the bio-ethic is concerned. Science can not remain morally neutral.

b. The role of the concept "scientism" in the actual way of thinking:

- 3 important steps are distinguished by A. Comte in the evolution of a human being.
 - 1. the theological step: humans cannot explain understandable phenomenon by religion.
 - 2. the metaphysical step: the appearance of abstract entities.
 - 3. the step of the positivism.
- Phenomenons are connected to laws. (Constant relation between phenomenons).

In the positivist attitude, science becomes the foundation of the individual and social life. The moral conscience is obliged to evolve as quickly as the evolution of the science as consequence of this positivist attitude. The result is an ethical revolution. Trying to define the actual concept "moral", a possible approach can be in connection with his hereditary nature: the moral conscience is the result of the heritage of the human feelings (example: compassion, devotion). Thus the "moral" is the result of the sociobiological evolution we transmit. This approach of the terminology "moral" can be confirmed by the inability of the human being to make a final law about human rights. It is necessary to consider an evolving bio-ethic, based on the evolution of the nature of the human being.

• Where would we situate homeopathy and CAM in this context?

Using the positivist attitude, homeopathy is based on the fact that it is a fully experimental science. But homeopathy exceeds this positivist attitude, keeping a "metaphysical" aspect. The homeopathic phenomena are only linked to the natural right.

c. Positivism.

Conventional medicine is based on scientism. It is important to underline that the representatives of this conventional science determine laws, allocations of budgets and the composition of the ethical committees. The National Ethical Committee is composed and directed by researchers who are at the same time judge and jury! Therefore we can understand that political action is based on ethical orientations submitted to the rules of the dominant science paradigm. Orientations are decided not only by a compromise between individuals but also by a social consensus. The actual ethic is indeed accepted by the majority of the people but it is not based on the individual rights of every human being. In this way it is immediately submitted to the legislative power.

The actual ethic is based on 2 principles:

- 1) <u>Difference between the ethic of conviction</u> and the ethic of responsibility (Theory of Weber)
- 2) Discussions as empirical tool to come to a consensus.

The ethic of conviction is based on the principles of the metaphysics and religion. On the other hand, the ethic of responsibility disregards these principles. The ethic of responsibility is more adapted to a rational approach of the problems caused by the progress of the medical research. When formulating a law, a consensus can be reached by discussion. Society confirms the accepted laws. These laws are the result of a dialogue based on the expression of all opinions above all convictions. References to "truths" or to the "absolute" must be avoided because interaction would not be possible anymore. It may become clear that the moralistic philosophy and the positive right have different subjects and methods. The positive right covers the practice, protects persons and punishes infringements: at this level a minimal consensus will be sufficient.

d. Access to the metaphysical dimension of the human being.

It allows describing the limits of positivism. Therefore it is necessary to look at the relation between the positive and metaphysical sciences. Agnosticism and Progress ideology (amelioration of mankind and well-being) dominate our actual society.

- A human being is unique and sensitive;
- A duality in science could exist: science can explain the universe but who explains science?
- Certainly there is a relation between science and spirit.

Positive sciences should only be an instrument. A human being uses this instrument, but should not be enslaved to it. Natural sciences show us how deeply we are anchored to the very depths of nature. These sciences teach us to know our impact and our responsibility to nature; a human being creates science but goes beyond this science by his spirit.

This last approach may be considered as individualistic and keeps no account with the social responsibility which is, as we have already seen, totally different. Must we accept to go on with the split between the social and individual ethic?

Because of the evolution of quantum physics, we know that homeopathy and the other CAM are not considered science as the other sciences are. In this connection we have an ethical problem. The individual approach dominates in homeopathy but the social responsibility of the medical doctor homeopath is the same as of every other medical doctor

2. The bio-ethic and its most important currents.

The most common definition of the bio-ethic could be formulated as following "science of morals". This definition is confusing because the reason for the existence of ethics is not scientific. All bio-ethical problems such as research on embryos and euthanasia divide our conscience. These problems also penetrate the field of contemporary homeopathy.

Let us reflect the origin of the word "ethic", originated from the Greek word "ethos" ("safe home"). Referring to this source, one finds that ethics is neither a matter of arguments, nor of concepts. Ethics is more a state of mind, a way of being in the presence of the pain appearing on the face of another. Emmanuel Levinas defines pain as "the impossibility of finding a safe home". So, it should be logical to consider ethical, all actions done with the expectation to make the world more liveable. Homeopathic medicine and CAM, like the whole humanistic world, is par excellence a medicine of hospitality, listening to the patient with the purpose of enlightenment of the pain by offering him a new "safe home".

It is interesting, in accordance with the discussions going on at this moment at international level about the factor "health", to explain two dominant ethical sensitivities:

- the first one is the "utilitarian ethic" predominant in the Anglo-Saxon world.
- the second one is the "deontological" inspires more the continental way of thinking.

We will place homeopathy and other CAM therapies in relation to the problems encountered concerning the national diversity of the concept of philosophy.

A. The utilitarian Ethic.

The emphasis is put on the "utility" of each action for "the highest happiness for the most possible number of people". The utilitarian concept evaluates the moral value of an action to its consequences (not the intentions but the consequences count). The founder (Bentham) of the utilitarian ethic said: "good is what is good for me without harming the other". The utilitarian ethic is also called "naturalistic" namely acting according to good is acting respecting the gifts of nature to us.

It is a philosophy proclaiming the "doctrine of enjoyment" and as such including the free transactions between persons under the form of a contract. The problem of a woman carrying a child for another woman or the selling of cosmetics is illustrative: why forbid when everybody enjoys it?

B. The Ethic of the Deontology.

The deontological ethic ("Deon"= Greek = what is necessary to do) is not based on the right of enjoyment but on the duty to the respect for the other person. Here one could say that it is a "person-bound" ethic. Kant is the symbolic person for this movement. Not only are the consequences of an action important but also the intentions preceding our behaviour. "Act in a way you should treat humanity as well as you would yourself and the other; always and at the same time as an aim and never only as a tool". We cannot accept a world where people consider their body as a business.

C. Applications to CAM.

Homeopathy and CAM were the object of so much scepticism in the 20th century. This is mainly because of the fact that they are integrating science and "non scientific" knowledge. They seem to leave the framework of the positivist medicine. To integrate homeopathy and CAM in our health service, they have to be in harmony on the ethical level. Ethical questions, typical for complementary and alternative medicine must be considered. What is needed to integrate them safely into the existing health system, offering patients and medical doctors a free choice of therapy?

a. Developing at European Union level, and in the world, legislation allowing the integration of CAM in the health services.

The integration of the practice of CAM and homeopathy in free medical practice and in the structures of hospitals is necessary. It is a matter of social and ethical good sense. For medical doctors, the social and collective responsibility is also linked to their deontological responsibility. By integration, it will be ethically possible to offer patients more medical approaches respecting freedom of choice even when s/he moves from one country to another.

b. CAM therapies have their own fields of action and indications and are not allowed to replace the conventional medicine with its specific indications.

It is necessary to define the indications for CAM; homeopathy and some CAM therepies are curative in certain clinical situations. In some pathologies, scientific studies showed positive results. On the other hand, their application may not be indicated in other specific situations and modern technology would be preferred in order to help the patient.

c. Problems related to life.

A medical doctor will be consulted regularly for problems related to "life". The medical doctor, having at his/her disposal complementary and alternative therapies, is more able to advise the patient about a medicine respecting natural rights. His advice can be an element for discussion in regard to a heavy technical intervention. On the other hand there must be a deontological ethic to this advice evaluating also what may be the consequence of this decision for the well being of the patient.

d. The freedom of choice for the patient as well for the physician.

This is a fundamental right, based on clear and unbiased information which a medical doctor can give to a patient. At this level the education of a medical doctor in conventional as well as in alternative medicine is necessary. After a medical diagnosis it will be possible, for this medical doctor, to offer his patient different possible available treatments. The patient can make his/her choice when s/he is well informed. When the physician has to make this choice, he has to consider all ethical aspects as well as the methods he considers using for treatment.

e. Homeopathic medicines.

Homeopathic medicines have very precise indications. Their action is proved by research and validated clinical trials (see further). Homeopathy is an experimental science, based on clinical research and verification. On the other hand, research gets only little support at the national level as well as the European or intercontinental authorities. CAM and especially homeopathy ask for validation and financial support by the authorised authorities so that from an ethical point of view the user of these products can get guarantees about safety and efficacy.

IN CONCLUSION:

Looking towards a more humanistic medicine, in contrast with a very technically and over specialized medicine, the reconciliation between scientific progress and respect for the human person must be a priority.

Therapies like CAM and homeopathy have several indications in the field of chronic as well as in the field of acute diseases; even within very extreme situations as we may see in the intensive care unit, homeopathy can help patients.

For the well-being of everybody, the development of research within CAM and homeopathy is necessary; funding it, in a correct way, is needed as is a good education in Medicine and in CAM for the physicians using CAM.

The patient becomes impatient.

When everything is regulated, a free choice for the patient and the medical doctor will be possible. Efficient results and the amelioration of a patient's health and welfare will be guaranteed.

Some ethical references:

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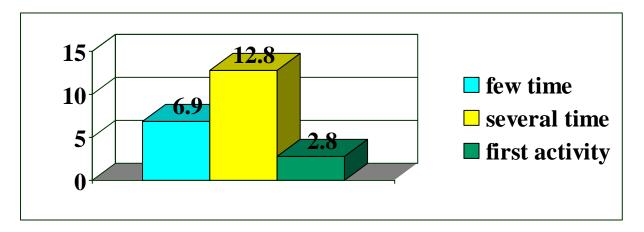
DELAISI de PERCEVAL G. "Le magasin des enfants" Editions F.Bourin`

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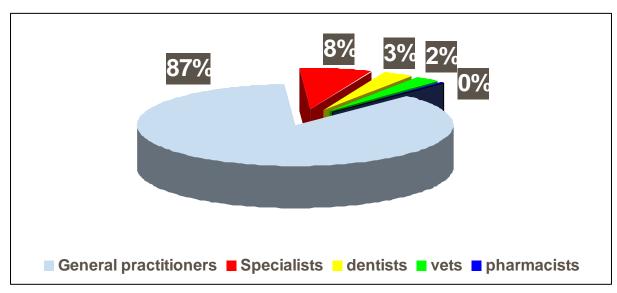
CHAPTER III

Framework of the practice: Belgium as example.

More than 22% of the family doctors prescribe homeopathic medication more or less on a regular basis. 3% of them prescribe homeopathy as a first choice.

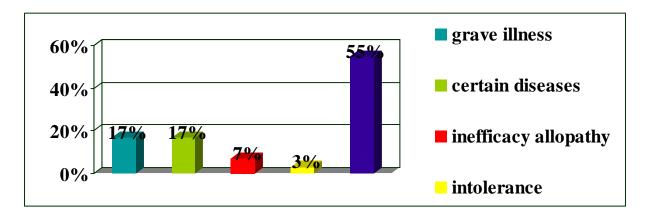


The profile of the medical doctor homeopaths, members of a Union shows that a majority (87%) are GPs.



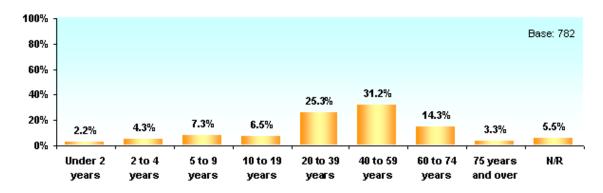
The reasons why patients ask for a homeopathic treatment are very various and are certainly not limited to "easy to cure" indications.

Inquiry of 6000 persons, representative of the Belgium population, 45% use homeopathy.

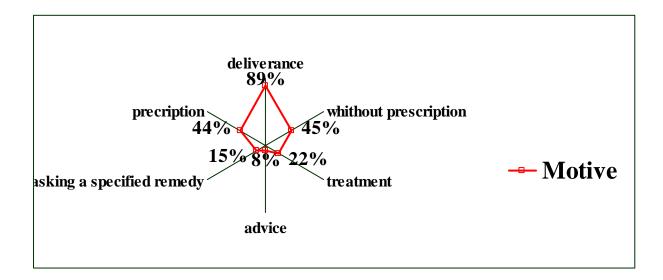


All ages are represented, from paediatrics to 75+. The group above the 55+ is considered to be the most expensive for the budget of the national health service.

3.1.2 Age group overall



The demand and delivery of the medication in the pharmacy was also scrutinized in the same inquiry. Auto-medication covers 15% of the demand; the physicians (prescriptions) are responsible for 44% and the pharmacists' advice cover 30%.



One may conclude that the use of homeopathic medication is widespread (even more than expected including self medication and pharmacists' advice).

Within the framework of the complementary insurance, reimbursement of prescribed homeopathic medicinal products is possible from 25% to 50% of the price.

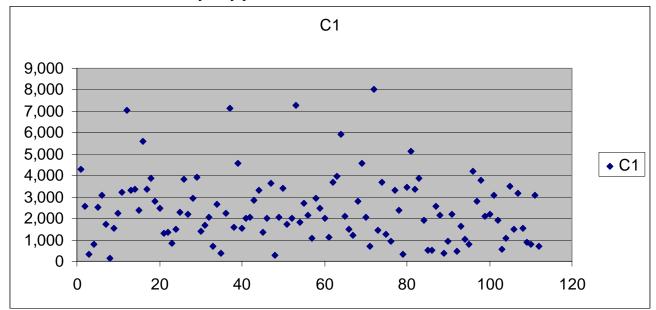
Several inquiries on medical doctor homeopaths show that most of them prescribe homeopathy within the framework of first line medicine.

Every MD receives, yearly, his individual profile of prescriptions of **medical imaging** and **clinical biology** from the National Institute of Health. We, regularly made a comparison between the profile of MD homeopaths and all other physicians.

52% of the accredited GP homeopaths sent their profile. The values of the consecutive years were put together and a year average calculated.

The year average of patient contacts was 2.415. 34% of the Belgium physicians are doing fewer consultations. 66% are doing more consultations.

If we consider the average amount paid back by the insurance for each individual patient contact concerning **medical imaging**, the value for this group is 2.6 meaning that only 26% of the Belgian physicians cost less. 74% of the physicians cost more than the group of homeopathic physicians.



Scheme 2: Distribution of the yearly patient contacts.

If we consider the total amount of yearly prescriptions of **clinical biology**, of MD homeopaths the worth is 2,9 meaning that 29% of the Belgian physicians prescribe less, 71% prescribes more. The average number of requested analyses for each prescription is higher under the MD homeopaths in comparison to the average of Belgian physicians (worth 3,7). MD homeopaths are prescribing more complete biological evaluation than the MDs but in a lower frequency. This means that concerning **the total amount of demanded medical analyses**, 37% of the physicians prescribe less than the MD homeopaths, 63% more.

If we consider the average amount paid back by the insurance on each individual patient contact (if we should have the same number of yearly consultations) concerning clinical biology the value by patient contact is 4,8 meaning that 48% of the Belgium physicians cost less, 52% more.

This confirms that the specific medical act of the homeopathic physicians creates no particular problems for social insurance. If the costs of the clinical biology are added to the costs of the consultations the total amount for the homeopathic group situates itself at the value of 3,3 meaning that 33% of the Belgian physicians cost less, 67% cost more to the national insurance service.

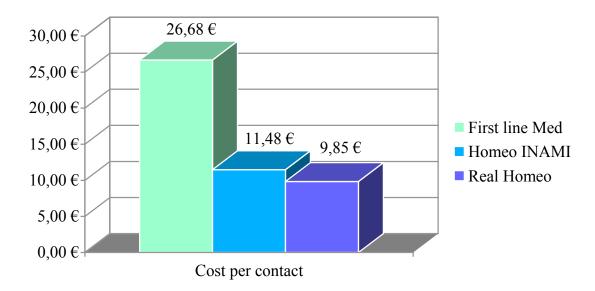
More information would be needed about the profile of the patients consulting a homeopathic physician, in comparison with the profile of patients consulting conventional physicians. If the practice of a homeopathic physician were completely different from the conventional one, an extrapolation could indeed have been biased. The same problem exists if the patients consult also, on a regular basis, conventional physicians for supplementary analysis. In fact, we are already sure that it is not the case, 50% of patients are asking for a Global Medical File (inscription) by a MD homeopath.

CONCLUSIONS:

- The practice of homeopathic doctors is part of the framework of medical practice. Clinical biology and medical imaging are used when necessary.
- No abnormalities are found concerning insufficient or exaggerated prescription profiles. The profiles of MD homeopaths are similar in comparison with the conventional colleagues.
- No significant difference in the prescriptions of clinical biology and medical imaging prescribed by MD homeopaths in comparison with the conventional colleagues.
- The <u>biological analyses</u> of the homeopathic physician are <u>more complete</u> and extensive.

Comparison of the prescription costs at each consultation.

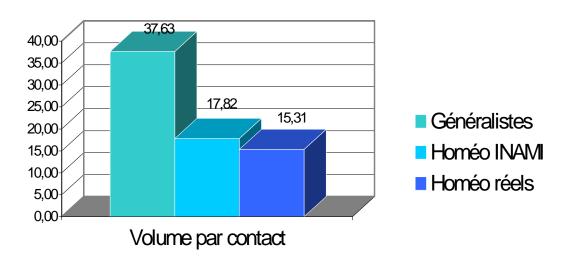
For GPs the cost of the prescription at each consultation is about 27 € GP homeopaths prescribe, at each consultation, conventional medication for about 12 €



The amount of patient contacts of MD homeopaths is based on the reimbursed consultations by the National Institute of Insurance Service (INAMI). A lot of patients are insured through private insurance companies and as such are not counted as patient contact but supply of medicines is counted. Therefore, the real number for consultations is higher and the real cost for each consultation must be corrected to 9,85 € per patient contact.

Some could say that this difference exists because the homeopathic physician treats less severe ailments. We know however that a homeopathic doctor treats chronic and severe diseases. We can justify and confirm these results by studying the volume of each prescription at each consultation.

volume per contact

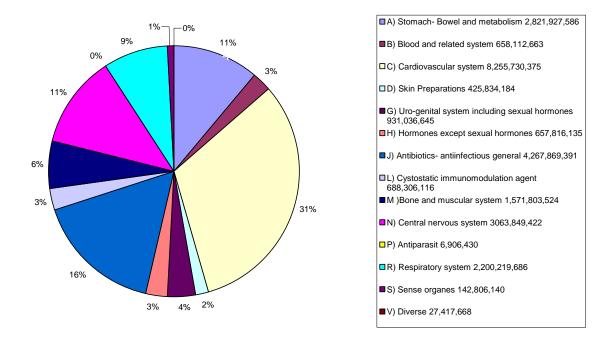


Comparison between medicinal products.

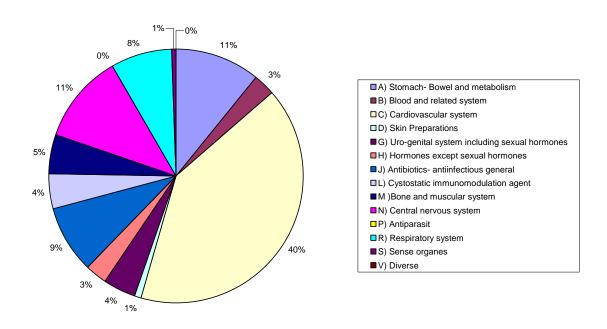
The 2 following tables show clearly that the homeopathic physicians prescribe relatively more conventional remedies linked to blood and cardio-vascular problems in comparison with all medical GP's.

On the other hand, MD homeopaths prescribe less in other sectors, such as NSAI and antibiotics. Here a difference of 50% is remarkable.

Group: all general practitioners



Group: general practitioners-homeopaths



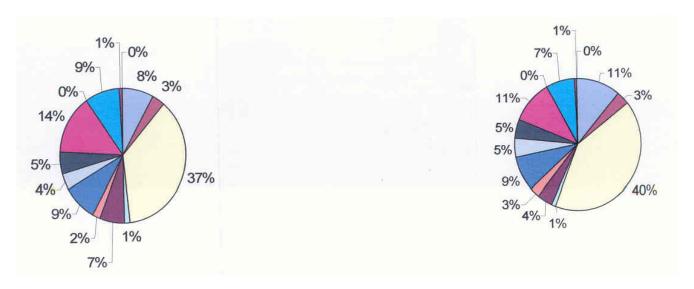
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E.C.H. - info@homeopathyeurope.org - L.M.H.I.

Mutual comparison between homeopaths.

Homeopaths few contacts

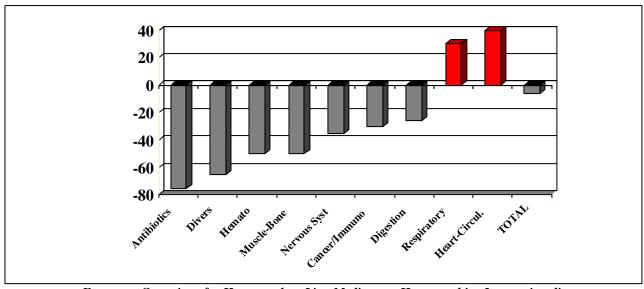
Homeopaths many contacts



Homeopathic doctors with many contacts (more than 1.394 in 6 months) prescribe relatively more conventional cardio-vascular remedies than the one with few contacts (less than 1.394). But Homeopathic physicians with few contacts prescribe still more than conventional colleagues.

This group of homeopathic physicians with few contacts prescribes also more hormones and remedies related to the central nervous system at each consultation. May be the reason is that they see a patient less frequently and the time between two consultation is longer, they have to foreseen patients with enough medicines to cover a larger period.

A homeopathic doctor sees more patients with respiratory tract problems than conventional colleagues. This is not the case for cardio-vascular problems, here no homeopathic alternative exists.



European Committee for Homeopathy - Liga Medicorum Homeopathica Internationalis

Conclusion of these surveys:

- The medical activity of the GP homeopath is done in the framework of medicine.
- Prescriptions of conventional remedies occur when necessary.
- The **amount of patient contacts** is **24%** lower for MD homeopaths in comparison with all GPs.
- The **cost of each prescription** of GP homeopaths for conventional remedies is **50** % lower (more or less 15 €)
- For hormonal treatments, uro-genital and **cardio-vascular pathologies**, homeopathy is not an alternative for the conventional treatment.
- On the other hand, there is a spectacular decrease in percentage of prescriptions of NSAIs and antibiotics. This is very important for health care in general because it reduces the risk of resistance against antibiotics and subsequent iatrogenic disease through NSAIs (stomach ulcers).
- All together knowledge and use of homeopathy can generate a considerable decrease of the volume and of the cost of the prescriptions at each patient contact (especially for antibiotics and NSAIs)

Of course this survey does not allow evaluation of the cost of homeopathic medicine because these data are not taking into account by the National Institute of Insurance Service (INAMI)

It would be interesting to analyse the number of contacts, by a single patient, with a conventional GP in addition to the contacts with a MD homeopath when it exists.

5 a year, is the average amount of contacts for each patient to a GP homeopath.

The strategy of a treatment (only conventional or only homoeopathy or both) depends on the diagnosis. Homeopathic therapy is only possible within the framework of medical practice taking into account the freedom of therapy for the medical doctor.

All these results are published (13) and some more facts are of interest:

The treatment by a homeopathic physician causes an important reduction in the consultations with another GP or a specialist (2/3 less). The patients in the worst physical condition at the start of the treatment derive the most benefit from homeopathic treatment. The average length of a homeopathic consultation is 37 minutes.

(13) Van Wassenhoven M, Ives G. An observational study of patients receiving homeopathic treatment. Homeopathy 2004 January, 93:3-11.

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As a result of a homeopathic treatment 52% of the patients are able to stop one or more conventional medicines. Particularly medicines for the central nervous system can be consequently reduced (21%) along with medicines concerning the respiratory tract (16%) and antibiotics (16%). The homeopathic physician prescribes only 1/3 of the total amount of medicines prescribed by a conventional physician. For the antibiotics this is even only 1/5. If we extrapolate this to all patients, in the assumption that every physician should prescribe homeopathy, this would give a **reduction of 2/3 on the budget of medicines**.

Through all these surveys we showed that homeopathy has a place and has to stay or be implemented at least within the general practice of first line medicine. There is no evidence of any medical deviant conduct by the homeopathic physician.

At the latest LMHI congress (May 2008) comparable results were presented for France, Italy and USA:

Chaufferin G. L'homéopathie est-elle coût-efficace? Homeopathic medicines represent 6% of distributed medicines but only 1% of the costs in medicines for the patients.

Rocco V. Measuring private homoeopathic practice in Italy. An important factor in the decision to come to homeopathy is MDs competence, education and experience.

Frye J. Comparing use of homeopathy with a practitioner and use as self-care in the U.S. 2002 National Health interview survey.

CHAPTER IV

Meta analyses – Systematic review

The « gold standard », accepted by everybody to evaluate the efficacy of a remedy is a meta-analysis or a systematic audit of RCTs. Since 1991, 6 comprehensive reviews concerning homeopathy were published.

The conclusion of all comprehensive systematic reviews was that homeopathy has a positive and specific effect greater than placebo alone. Several randomized and controlled studies (RCT) showed a statistic significant difference between homeopathy and placebo.

Report about all comprehensive systematic reviews on homeopathic trials.

Kleijnen en al. 1991 (14) *British Medical Journal*. 105 studies with interpretable results. Meta-analysis based on validated criteria.

- 77% of the studies show positive result for homeopathy.
- The results are mostly favourable for homeopathy regarding the quality of trials.
- « There is a legal argument for further evaluation of homeopathy".

Boissel en al. 1996 (15) Report for the European commission. 15 studies. Inclusion of only very rigorous studies (highest quality).

- Combined p-values for the 15 studies is significant. (p = 0.0002).
- « It is evident that homeopathy is more efficient than placebo".
- Little evidence for non-published negative results.
- Further research is justified.

Linde en al. 1997 The Lancet. 89 studies.

- «Odds ratio» combined 2.45 (95% CI, 2.05-2.93) in favour of homeopathy.
- «Odds ratio» for the best 26 studies was 1.66.
- It is not possible that the clinical effects of homeopathy are due completely to placebo.

Linde and Melchart 1998 (16) *Journal of Alternative and Complementary Medicine*. 32 studies, inclusion of studies on invidualised homeopathy only (19).

- Individualised homeopathy is more efficient than a placebo: the value of the combined coefficient was 1.62 (95% CI, 1.17-2.23).
- Further pragmatic research is justified.

Cucherat en al. 2000 (17) European Journal of Clinical Pharmacology. 16 trials representing 17 comparisons with placebo (based on data from the Boissel 1996 study).

- Several studies have positive results. More trials have a positive result than would be expected to chance alone.
- Publication bias is unlikely.
- More clinical trials are needed.

Shang & al. 2005 (17a) *Lancet*. 110 trials included but conclusions are taken from a few post-hoc selected studies only (N=8 or 7%).

- Quality of studies is on the average better than those made with conventional remedies.
- The authors concluded that no significant effect exist with homeopathic medicines.
- Today it has been proved that this conclusion is based on an amalgamation of bias: selection bias, post-hoc criteria and heterogeneity (17b).

Comments on meta-analyses:

The fact that some meta-analyses showed some positive evidence for homeopathy is remarkable because meta-analyses are far from appropriate when trials are extremely heterogeneous (as in homeopathy) not only in results but also in the interventions and health conditions under study and when a therapeutic system works in some but not all indications.

One publication, namely GRECHO (18) study takes an excessive place and considerably influences the results of all these audits (especially in Shang: 1/7 = >15%). Opium and Raphanus are administered to activate the intestine activity after operation. These two medicines were compared with placebo. No positive result was obtained. However the individuality, a basic principle of homeopathy, was not taken into account.

The major problem with this type of analysis is linked to the hypothesis at the beginning: "homeopathy is not better than placebo". What should happen if we should look at the zero-hypothesis "the conventional medicine is not better than placebo" taking into account all negative results, even not published studies? Is this a question of general interest? Why is this question of interest for homeopathy? From a scientific point of view this question has only sense for those who are thinking, a priori, that a therapeutic approach is only placebo.

Recently the zero-hypothesis was reformulated as "homeopathy functioned not better as a placebo in a specific case". This hypothesis is corresponding to systematic conventional research and as such cannot be questioned.

It is also a solution to the problem of heterogeneity of medical conditions. 17 systematic reviews or meta-analyses focused on RCTs of homeopathy in 15 specific areas were performed: anxiety, childhood diarrhoea, chronic asthma, delayed-onset, muscle soreness, dementia, depression, headache and migraine, HIV/AIDS, induction of labour, influenza treatment and prevention, osteoarthritis, post-operative ileus, seasonal allergic rhinitis (hay fever) and vertigo.

This critical approach has been explained by Jonas, Kaptchuk and Linde in 2003 (19). The **level I of evidence** is reached for childhood diarrhoea and seasonal allergic rhinitis. Other meta-analysis showed this same level for allergic rhinitis (20), post-operative ileus (21), rheumatoid arthritis (22) and the protection to toxic substances (23).

Level IIa of evidence is obtained for asthma (24), fibrositis (25), influenza (26), muscular pain (27), otitis media (28), several pain sensations (29), side effects of radiotherapy (30), strains (31) and infections of the ear, nose and throat (32).

Level IIb of evidence is obtained in the treatment of anxiety (33), hyperactivity disorders (34)(42), irritable bowel (35), migraine (36), osteo-arthritis of the knee (37), premenstrual syndrome (38), pain associated with unwanted post partum lactation (38b), prevention of nausea and vomiting during chemotherapy (39), septicaemia (40) and post-tonsillectomy analgesia (41).

Even if this approach has the advantage to correspond to common criteria of the conventional medicine, based on experiments, it stays very limited and does not analyse the daily practice of the homeopathic GP. Further phases are needed because the general practice is more than searching the treatment for a specific pathology. The GP and especially the one specialized in homeopathy is searching for a global amelioration of the health of the patient. He considers a wider frame than only the treatment of a disease; he will consider also the diet, the psychological state of the patient, his professional activities, the environment, etc.

The practical choice of a treatment for a specific patient is only little helped by the RCT results; they are obtained in "an ideal artificial situation" far from the personal context of the patient. The homeopathic diagnosis is more than a search to a disease; it is an approach including the whole person, with the aim of an individualized and global treatment. The method of evaluation has to be adapted to this reality; today Bayes' statistics authorize such research (see further).

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CHAPTER V

The results of the 'ECHO' - study

'ECHO' refers to surveys looking at Economic, Clinic and Humanistic Outcomes.

In the literature 19 publications, using validated scores concerning quality of live (QoL), are found to evaluate the efficacy of homeopathic medicines. 19.804 patients are included in the different studies. A **level IIIa of evidence** is obtained for all ECHO-studies, all diagnosis merged.

A first group of studies compares the QoL score before and after the treatment. The control group is the group itself before treatment. The improvements are statistically and clinically significant, all diagnoses merged. Some diagnoses were analysed especially: asthma in children, headache, cancer patients, anxiety and depression after stopping the estrogenic hormonal treatment because of breast cancer, allergies, general problems, intestinal disorders, anxiety disorder, depression and skin problems. These are also the most common diagnosis in general practice.

A second group uses an external control group treated with conventional medicine. The results of these studies show that the homeopathic treatment is just as efficient as the conventional medicine in general practice. Respiratory problems, chronic problems in the ear, nose and throat area, as for example sinusitis, are considered as well as problems during pregnancy.

A third group uses the score of quality of life during a controlled and randomised study. For vertigo homeopathy is just as efficient as conventional medicine. In a study on asthma, the quality of life at the start of the study is so high that no significant difference could be found.

Condition/Study	N	Design QoL	Test group	Control group	Results
Becker-Witt et al. (54, 55)	2851	Prospective observational study. MOS SF-36	Homeopathy	-	Significant and relevant improvement of the SF-36
Bordet et al. (60) Menopausal hot flushes. 6 months	438	Prospective observational study. Multicentric (99 MD) Not validated double QoL score	Homeopathy	-	Significant and relevant improvement on both QoL scores (daytime / sleep)
Dias-Brunini. 2002 (45) Asthma – pediatrics 6 months	51	Prospective observational study. AUQEI QoL score applied to children.	Homeopathy	-	QoL score from 42,27 to 54,94, significant statistical increase.
Goossens & al 2008 (60b) Hay fever	74	Prospective observational non comparative study. RQLQ QoL	Homeopathy	-	Significant improvement after 3 and 4 weeks
Guthlin et al 2001 (49) All conditions <4 years	951	Prospective observational study. MOS SF-36	Homeopathy	-	Number of patients too small to find valid results.
Guthlin et al 2003 (57) All conditions <4 years	750	Prospective observational study. MOS SF-36	Homeopathy	-	QoL improved in most dimensions highly significantly
Jong et al 2006 (51) Respiratory and ear complaints 7-14-28 days, final results 2006.	2055	Prospective observational study. HSQ-12; HSQ-5	Homeopathy	Conventional	No significant differences in duration of illness, response to treatment, patient satisfaction and adverse effects.
Heger et al 2001 (56) Respiratory and ear complaints 14-28 days	456	Prospective observational study. HSQ-12; HSQ-5	Homeopathy	Conventional	Homeopathy at least as effective as conventional medical care (64,3% ><56,6%). Adverse effects 7,8% versus 22.3%.
Hochstrasse B. 1999 (53) pregnancy <9 months	205	Prospective observational comparative study. SEIQoL	Homeopathy	Conventional	Lower QoL in the homeopathic group (two different populations, comparisons impossible)
Muscari-Tomaioli et al 2001 (50) Headache 6 months	53	Prospective observational study. MOS SF-36	Homeopathy	-	The mean and median scores of all QoL dimensions rose. Strongest results in the "bodily pain" and "vitality" parameters p<0.0001

Spence et al 2005 (59) Wide range of chronic conditions	6544	Prospective observational study	Homeopathy	-	Positive health changes in routine homeopathic hospital practice
Strosser et al 2000 (52) Vertigo 6 weeks	119	Double blind Comparative study. MOS SF-36	Homeopathy (Vertigoheel)	Conventional (Betahistin)	Significant amelioration of the physical and mental health with homeopathy. Equivalent efficacy of the two groups.
Thompson et al 2002 (46) Cancer 5 consultations later	52	Prospective observational study. EORTC QLQ-30 QoL score	Homeopathy	-	Improvement in 75% of the patients.
Thompson et al 2003 (43) Management of symptoms of oestrogen withdrawal in women with breast cancer.	40	Prospective observational study.	Homeopathy	-	Significant improvements in anxiety, depression and QoL.
Wassenhoven et al 2003 (48) All conditions 6 months	1025	Prospective observational study.MOS SF-36 & DUKE QoL scores	Homeopathy	-	Qol score differences: Allergic conditions +7,987; Gen. health problems +10,198; Bowels +8,189; Muscles & bones +0,764; Stress, anxiety, sadness +6,041; Nose, ears +4,677; skin +6,395. Small but significant statistical improvement.
Weber et al 2002 (47) Acute sinusitis	63	Non-randomised, controlled clinical trial. HCG-5 QoL score	Homeopathy + herbal ther.	Conventional therapy	Equally effective (or ineffective)
White et al 2003 (44) Asthma – pediatrics / 12 months	96	Randomised placebo controlled trial using QoL subscale of the Childhood Asthma Questionnaire	Homeopathy adjunct to conventional treatment	Placebo adjunct to conventional treatment	No statistically significant changes in the QoL score, small severity improvement. NB: very high initial QoL score
Witt et al 2005 (58) All conditions 3,12 and 24 months	3981	Prospective multicentre cohort study. QoL score	Homeopathy	-	Marked and sustained improvements.

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Studies about *Cost-Efficiency* of the treatment are mostly requested by the authorities. Here also a **level IIIa of evidence** is obtained for all analysed aspects.

The reason for this interest is multiple. The cost of the conventional medicine is more and more a problem for certain patients. The survival of our social security systems is threatened by these enormous costs.

The available data (15 studies -9.932 patients) show that a reduction of the total cost for the patient is possible maintaining a global efficacy when using homeopathy.

Again a first group of studies compares the same cohort of patients before and after the study. The control group is the group itself before treatment. The monetary savings achieved by practising homeopathy are statistically and clinically significant for all diagnoses merged. Some diagnoses are especially analysed such as otitis media, atopic eczema and allergies, rheumatoid arthritis and anxiety disorders.

A second group uses an external control group treated this time with a conventional treatment. The results of these studies confirm that homeopathic treatment in general practice allows savings under all conditions. Some data were especially analysed such as the seasonal allergic rhinitis, asthma, atopic eczema, food related allergies, chronic allergic rhinitis, anxiety disorders and acute rhino-pharyngitis.

General conclusions of this literature review

Besides the general analysis and conclusions about the effects of homeopathy, efficacy has been proved using as RCT evaluation as well rather than QoL scores for the allergies under all their aspects. The prevalence of these problems is growing in the world population. For authorities this is also a very big problem; it is the cause of absenteeism. An important social cost is linked to these problems. Homeopathy can be a cheap and efficient solution.

Το ηλεκτρονικό αυτό έντυπο παρέχεται από την

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CHAPTER X

Conclusions

- Homeopathy is mostly used in medicine in the framework of general practice (but also by gynaecologists, paediatricians, etc) and is used by patients of all ages.
- possible therapies that could be used to improve his/her health and also about the The respect for patients' rights means that the patient must be informed about all therapeutic possibilities of homeopathic medicines even when in hospital.
- necessary that medical doctors are dedicated to the practice of homeopathy. the only possible risk when using homeopathy as treatment. That is why it is The absence of a correct medical diagnosis at the start of a treatment is currently
- homeopathic practice in the scientific framework of the general practice The level of evidence obtained for numerous diagnoses is sufficient to accredit
- public health. These The use of homeopathy in general practice may imply a reduction in costs for in the number of days absent from work conventional remedies, a reduction in the number of consultations and a reduction savings are coming from a reduction of prescribed
- demand of the population. Therefore it is important to promote information sessions and education into homeopathy in the framework of the general practice. The number of competent homeopathic physicians is not sufficient to cover the
- supported by the public health authorities. University research on homeopathy must be encouraged, stimulated and
- Basic research results and veterinary research results are confirming the obtained results by paradıgm. humans. This is a specific effect supported by a new scientific
- homeopathic method. The internal evidence is validating and confirming the effects of the medical

amplified. Objective information is needed for patients. general medical practice frame. accepted The facts proposed in this report are indisputable. Homeopathy must be homeopathy encouraged in the frame of medicine. in the scientific framework of medicine, Research must be supported and especially in **Education** in

Condition/Study	N	Design Economic Survey	Test group	Control group	Results
Haselen et al 1999 (69) Rheumatoid arthritis	89 (random sample out of 427)	Retrospective study	Homeopathy (n=89) Acupuncture (n=4)	-	32% of patients reduced conventional drugs. Total costs to treat 89 patients were 7129 GBP (including medication, staff time and diagnostic procedures - 29% of the costs for consultation, 22% for conventional drugs)
Jain 2003 (71) Reduced costs by homeopathic drug prescription	109	Prospective uncontrolled observational study	Homeopathy	-	Savings by homeopathic treatment calculated by deducting costs for homeopathic medication from conventional medication (hypothetical) for same diagnosis and same duration amounted to 60.40 Pound Sterling.
Rossi et al. 2006 (74) Respiratory Diseases	99	Retrospective observational study	Homeopathy	Conventional	Reducing conventional remedies use, 40% costs saved.
Schafer et al. 2002 (65) Hay fever, asthma, atopic eczema, food hypersensitivity		Population-based nested case control study	Alternative Medicine	No alternative medicine	26.5% used CAM, patients were significantly younger and better educated. CAM mostly provided by MDs, median costs for single and entire treatment of 4 and 205 euro. CAM User scored efficacy of conventional therapy lower than non user (p<0,001)

Condition/Study	N	Design Economic Survey	Test group	Control group	Results
Sevar. 2005 (75) All conditions	455	Prospective cohort study.	Homeopathy	-	Conventional Drug cost saving of £39,90/patient/year.
Taïeb et al. 2003 (73) Chronic allergic rhinitis.	300	Prospective, comparative cohort study	Homeopathy (HM)	Conventional treatment (CM)	At 3 months SF-12 score on physical dimension HM 51,8; CM 47,9 (p<0.05). Lowering of cost of care for patients from 45,74€ for CM to 27€ for HM. Lowering of cost of care for the social security system with 50% for patients using HM.
Trichard et al 2003 (66) Anxiety disorders	394	Prospective, comparative cohort study	Homeopathy	Conventional treatment	The homeopathic drug strategy produced equivalent results but less overall costs reimbursed by the national health system
Trichard et al 2003 (67) Acute Rhinopharyngitis	499	Prospective, comparative cohort study	Homeopathy	Conventional Therapy (antibiotics)	Comparable overall cost between both treatment strategies but less sick leave in the homeopathic group
Trichard et al. 2003 (68)	5549	Cross-sectional descriptive survey	Homeopathy	-	Only costs for medication included – average overall cost 6.78 € of which 3.78 € were reimbursed
Wassenhoven et al 2004 (72) All conditions.	782	Observational unselected study and comparison with nationally available data (secondary sources)	Homeopathy	-	Following homeopathic treatment there were significant reductions in consultations with other specialists and generalists, and in the cost of treatment. €370 compared with €287 The largest cost savings were made by patients with the worst ratings of their physical condition prior to seeking homeopathic treatment.
Witt et al. (75b) Atopic eczema	135	Prospect., comparative cohort study	Homeopathy	Conventional treatment	Comparable efficacy but fewer costs for the homeopathic group.

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CHAPTER VI

Internal evidence - Heuristic

Homeopathy is a medical practice aiming at strengthening the natural homeostasis of the body and stimulating the immune system. Homeopathy acts following the similarity principle; that means that the symptoms are treated with a medicine containing a substance causing similar symptoms in a healthy person. For example onion can be the cause of a watery discharge of the nose and eyes. A medicine prepared from onion, namely Allium Cepa, can treat patients who have these symptoms during a coryza or allergic rhinitis accompanied by irritating discharge from the nose.

The law of similars has to be respected during clinical and fundamental studies. Already 20 years ago a new paradigm allowing explanation of the homeopathic effects was developed. It is the paradigm of the « *Body signifiers* » (76). It explains why the law of similars has to be respected in research protocols on homeopathy; the tested medicine must be significant for the research subject (cell, plant, animal or human). A databank of experiments on homeopathy is regularly updated and available (77) today.

A. Pure experimentations or provings.

Homeopathic medicine is the result of the experimentation initiated by Hahnemann. This physician wanted to understand the effect of the prescribed medicines and that is the reason why he first experimented with these medicines on himself, and later on, other volunteers.

These experiments on "healthy" volunteers has never ceased for two centuries.

The medicine is taken by a volunteer for at least two consecutive days. The symptoms, developed by the volunteer after taking the medicine, are observed and noted very carefully. Afterwards all these symptoms are converted into repertorial language (integrated into existing rubrics or creation of a new rubric). The quality of each collected symptom is more important than the quantity of symptoms. Each proving result (symptom linked to a homeopathic medicine) has to be confirmed by other experiments and, later on, in the clinical practice. These experiments are standardized now and are realised on a regular basis a with placebo control (78).

As such, each symptom of the Materia Medica can be described with a certain level of evidence. The higher the level of evidence for the symptom linked to a medicine, the more the medicine used has a chance to cure the patient; that means the more this medicine can influence the organism to which it is administered.

⁽⁷⁶⁾ Bastide M. & Lagache A. Revue Intern. Systémique, 1995;9:237-249 + Altern Ther Health Med. 1997;3:35-9

⁽⁷⁷⁾ Van Wijk R, Albrecht H. Proving and therapeutic experiments in the HomBRex basic homeopathy research database. *Homeopathy*. 2007;96:252-257.

⁽⁷⁸⁾ Dominici G, Bellavite P, di Stanislao C, Gulia P, Pitari G. Double-blind, placebo-controlled homeopathic pathogenetic trials: Symptom collection and analysis. *Homeopathy.* 2006;95:123-130.

The more "significant" symptoms the patient has in common with the medicine, the more spectacular and complete will be the effect of the medicine. This is the globality principle in homeopathy.

A pure experimentation (proving) can be compared with a qualitative experiment, phase I, in conventional medicine. The homeopathic pharmacopoeia contains several thousands of different medicines; for each medicine many modalities (79) of symptoms exist and are encoded in our homeopathic repertories.

The analysis of the provings' publications authorizes a **level of evidence IIb** for this experimental (80) step. An audit of all English provings' publications done from 1945 to 1995 was published (81) in 1998 and other publications are in preparation. In future it will be possible to reach **level of evidence I** for these experiments.

At each LMHI congress new provings (or confirmation of ealier provings) are presented. In May 2008 the following provings were presented (see proceedings of congress):

Hydrogenium peroxidatum – H2O2. Dominici G. Double-blind, randomized, placebo controlled design; 16 provers revealing several symptoms clinically verified on human and animals.

Latrodectus Mactans Tredecimguttatus. AFADH – Fayeton S. Open design; 8 provers revealing groups of symptoms clinically verified.

Potentilla Anserina. Janssen JP. Multi-centric, prospective, double-blind design; 10 provers revealing 27 groups of symptoms.

Plutonium's Peaceful Brother: **Neptunium muriaticum**. Lustig D. Placebo-controlled design; 19 provers revealing 315 symptoms distributed into 12 groups of characteristic symptoms.

Brazilian Pathogeneses: **Helleborus Niger**. Marim M. Third confirmation, multicentric international design; 4 groups of symptoms are regularly recorded.

Sutherlandia Frutescens. Ross A, Webster H, van der Hulst N. Double-blind, placebocontrolled design; 24 provers revealing 15 symptoms correlated with the traditional use of the plant (restorative tonic in HIV patients).

Erythrina Lysistemon (African Coral Tree). Ross A, de Beer E. Triple-blind, placebocontrolled design; 32 provers revealing 25 symptoms.

Lobelia Cardinalis. Scheepers L. Open design; 7 provers revealing 32 symptoms.

Galium Aparine. Scheepers L. Open design; 8 provers revealing 18 groups of symptoms.

Ytterbium Nitricum. Vicol M, Cristescu LM, Ivanciu NV, Dobre ML, Sumbasacu M, Oprea AM, Goiceanu DM, Dragusanu O, Binder-Hampel A, Stanciu AM, Struza CM. Open design; 13 provers revealing 32 symptoms.

Hecla Lava. Multicentric international design.

Actually the best design are considered: Double-blind, symmetrical, three arms, placebo controlled (Möllinger H.).

- (79) The modality of a symptoms permits the differentiation between two medicines.
- (80) Walach H & all. Homeopathic proving symptoms: result of a local, non-local, or placebo process? A blinded, placebo-controlled pilot study. $Homeopathy~2004~n^{\circ}93,~179-185.$
- (81) Dantas F, Fisher P. A systematic review of homeopathic pathogenetic trials published in the United Kingdom fromp 1945 to 1995. In: *Ernst E, Hahn EG. Homeopathy A critical appraisal* 1998. Butterworth-Heinemann, United Kingdom.

B. Clinical verification of the homeopathic symptoms.

Symptoms obtained by pure experimentation must be confirmed by clinical results; the clinical validity of every symptom linked to a homeopathic medicine, as well as the totality of the symptoms (global picture of the medicine) must be verified. Traditionally experts in homeopathy were references for this clinical verification of homeopathic symptoms; this is **level of evidence IV.** Expert advice is very common in medicine, as example, the "ideal" value for the cholesterol in adults is actually, according to experts, 1,9g/l; it is the same level of evidence (UCL 2007).

The homeopathic Medical Doctor today uses computers in daily practice allowing a new approach for the clinical verification of homeopathic symptoms using a new type of statistical analysis.

Two statistical techniques are possible in case of retrospective analysis:

- * Either considering only indisputable results of prescriptions, failures or spectacular positive results. The analysis consists of looking at a possible link between this result and the selected symptoms of the patients used for the choice of the medicine. This method approximates the traditional analyses of experts. The results (82) make a strong connection between the results obtained by pure experimentation and the clinical efficacy of the prescription. At the end of this process, a table of the characteristic symptoms (or groups of symptoms) forming the picture of a homeopathic medicine can be established and verified. See a published example (83) in the references.
- * Or applying the theorem of Bayes on the same clinical database. Here all values are expressed as prevalence and compared to the remainder of the population (Likelihood ratio LR or probability factor as a link between the symptom of a medicine and the obtained clinical results). This method can be applied on a retrospective (84) as well as on a prospective (85) design.

Thanks these statistical results, a **level of evidence IIIb** is reached and we hope that other groups will participate to reach **level of evidence IIIa** in the near future.

The clinical verification of homeopathic symptoms is an internal validation of the basic principles of homeopathy and results can be used for improving the daily practice very soon.

⁽⁸²⁾ Van Wassenhoven M. Towards an evidence-based repertory: clinical evaluation of Veratrum Album. *Homeopathy* 2004:93, 71-77. First line medicine – Clinical verification – Verification of homeopathic symptoms ISBN (83) CCRH. Damiana – A Multicentric Clinical Verification Study. *Indian Journal of Research in Homeopathy* 2007 vol 1 n°1.17-23

Table of recent publications of clinical verification of homeopathic symptoms.

Condition/Study	N	Design	N Sympt	N Rem	Results
Van Wassenhoven.	2148	LR	>230	100	Symptoms - Similarity -
(82). (2005)		retrospective			Globality
CCRH (83)	3032	Trad. Method	?	1	Symptoms
Damiana (2007)					
Rutten & all (86)	4094	LR	6	75	Similarity
(2008)		Prospective			
Araujo (*).	5	Trad. Method	?	1	16 groups of symptoms -
Anacardium					Similarity (constitution)
orientale (2008)					
Gnaiger & all (*)	25	Trad. Method	?	1	6 groups of symptoms -
(86b)					Similarity (constitution)
Petroleum (2008)					
Dominici (*)	18	Trad. Method	10	1	Symptoms of proving –
Hydrogenium					Similarity
peroxidatum (2008)					
AFADH (*)	4	Trad. Method	?	1	24 groups of symptoms -
Latrodectus					Similarity (constitution)
Tredicim Guttatus					
(2008)	-	T 1 1 1 1	0	1	26
AFADH (*)	5	Trad. Method	?	1	36 groups of symptoms -
Tarentula Lycosa					Similarity (constitution)
(2008)	10	T 1 M (1 1	0	1	C
Louis (*)	12	Trad. Method	?	1	6 groups of symptoms -
Borax (2008)	2	T 1 M (1 1	0	1	Similarity (constitution)
Lustig (*)	2	Trad. Method	?	1	1 groups of symptoms -
Neptunium					Similarity (constitution)
muriaticum (2008)	-	T 1 M.41. 1	0	4	5
Marim & all (*)	5	Trad. Method	?	4	5 groups of symptoms -
(2008)					Similarity (constitution)

⁽⁸⁴⁾ Van Wassenhoven M. XIX GIRI meeting "A Universal approach to health: the intelligent body" – Retrospective LR study. 2-4 December 2005 Monaco. www.giriweb.com

⁽⁸⁵⁾ Stolper CF, Rutten ALB, Lugten RFG, Barthels RJWM. Improving homeopathic prescribing by applying epidemiological techniques: the role of LR. *Homeopathy* 2002;91, 230-238. & Rutten ALB et al. Repertory and the symptom loquacity: some results from a pilot study on LR. *Homeopathy* 2004: 93, 190-192. & Rutten ALB et al. LR onderzoek: uitkomsten September 2005. *Similia Similibus Curentur* 2005; 35:4, 9-12.

⁽⁸⁶⁾ Rutten ALB, Stolper CF, Lugten RFG, Barthels RWJM. New repertory, new considerations. *Homeopathy* 2008;97:16-21.

⁽⁸⁶b) Gnaiger – Rathmanmer J, Schneider A, Loader B, Böhler M, Frass M, Singer SR, Oberbaum M. Petroleum a serie of 25 Cases. *Homeopathy* 2008; 97:83-88.

^(*) Proceedings of 63rd LMHI congress 2008 (Belgium)

Condition/Study	N	Design	N Sympt	N Rem	Results
Petrucci (*)	8	Trad. Method	8	1	Symptoms of proving –
Falcon Peregrinus					Similarity
Disciplinatus (2008)					
Pla (*)	2	Trad. Method	95	1	7 groups of symptoms -
Salix Fragilis (2008)					Similarity (constitution)
Scheepers & all (*)	37	Trad. Method	38	6	Symptoms + 13 groups of
(2008)					symptoms - Similarity
					(constitution)
Servais & all (*)	11	Trad. Method	220	1	Symptoms
Petroleum (2008)					
Stolper & all (*).	26	Trad. Method	23	2	Symptoms of proving –
(2008)					Similarity
Uyttenhove (*)	300	Trad. Method	6	1	Symptoms of proving –
Cheirantus cheiri					Similarity
(2008)					
Uyttenhove & all (*)	262	Trad. Method	?	1	Symptoms of proving –
Hecla Lava (2008)					Similarity

^(*) Proceedings of 63rd LMHI congress 2008 (Belgium)

Total: **9.996 patients** are already included in recent systematic clinical verification of homeopathic symptoms. This number will increase very rapidly with the creation of an international Databank of clinical case in Italy. (Cli-Fi-Col project).

Conclusions on internal evidence:

Taking the obtained and verified results into account, homeopathy as medical practice can be confirmed as a validated medical method. Of course more research is necessary and welcome but the obtained level of evidence justifies the maintenance and development of homeopathy in the framework of medicine.

CHAPTER VII

The homeopathic medicine has a specific activity.

The nature of the homeopathic medicinal products is, for some, a factor of resistance (see Chapter I) even if the **level of evidence** for the efficacy of homeopathy within the general practice is already high as we have seen. In fact, 75% of the homeopathic prescriptions are molecular concentrations and as such would not be questioned by the believers of the molecular paradigm. In fact, proving an effect of the highest homeopathic dilutions-dynamisations is not aimed at questioning the molecular paradigm. It is only proving that, outside the molecular paradigm, there is place for other paradigms that could be applied for analysing radiations, psychoanalysis, acupunctural stimulations, high diluted-dynamized homeopathic preparations, etc. Actually, the proof of the action of the highest dilutions-dynamisations has reached **level of evidence IIa** and even **level of evidence I** for some.

Several professors at university investigated all the published literature about this subject at the request of the ECH (European Committee for Homeopathy)(87). New references are added for the period 2005-2008.

A/ The cheapest experimental model, easy to realise and reproduce, is probably "the acetylcholine induced contraction of rat ileum". This is a validated scientific model (Chang FY, Lee SD et al. Rat gastrointestinal motor responses mediated via activation of neurokinin receptors. J. Gastroenterol Hepatol 1999;14,39-45). This model was applied first to homeopathic preparations by A. Cristea, a Rumanian researcher, using this model for the verification of very high dilutions of Belladonna. The results were published. (Bastide M (ed). Signals and Images. Kluwer Academic Publishers 1997;161-170).

Professor Wolgang SüB of the Institute of Pharmacy of the University of Leipzig used this model to test the transition of a homeopathic medicine (in this case, Atropinum sulfuricum D60) from the original liquid form to tablets. As usually several controls were done. The monohydrate α -lactose tablets impregnated with a high dilution of Atropinum show a systematic efficacy opposite the anhydrous α -lactose tablets. This means that the quality of the tablets can be tested now before the pharmaceutical commercialisation (constant reproducibility). This very simple model shows that the activity of the high diluted homeopathic medicines is beyond all doubt. (Schmidt F, SüB WG, Nieber K. Invitro Testung von homöopathischen Verdünnungen. *Biol. Med.*/Heft 1/February 2004;32-37).

B/ It took some time before another scientific model could be accepted by the scientific community. The first publication was done in 1991, but it was only in 2004 that the results were accepted for publication by "Inflammation Research", a peer reviewed scientific journal. This model is different to that of Benveniste; he used the same control but not the same activator.

(87) Priorities and methods for developing the evidence profile of homeopathy: Recommendations of the ECH GENERAL ASSEMBLY – XVIII Symposium of GIRI. *Homeopathy* 2005;94:107-124.

Professors Marcel Roberfroid and Jean Cumps of the «University of Louvain», department of Pharmacy, and respectively coordinator of a multi-centric European survey (4 laboratories) and responsible for the statistical analysis, wrote the protocols of this study that showed a clear inhibition of the degranulation of the human basophils by high dilutions of histamine ($10^{-30} - 10^{-38}$ M). This inhibition becomes evident by the coloration of alcian blue. This multi-centric study is confirmed afterwards in three laboratories by using flux cytometry and in one laboratories using freed histamine. These observations are irrefutable acknowledged the editor of "Inflammation Research". (Belon P, Cumps J, Ennis M, Mannaioni PF, Roberfroid M, Sainte-Laudy J, Wiegant FAC. Histamine dilutions modulate basophil activation. *Inflamm. Res.* 2004;53;181-188), (Sainte-Laudy J, Belon P. Improvement of flow cytometric analysis of basophil activation inhibition by high histamine dilutions. A novel basophil specific marker: CD 203c. *Homeopathy*. 2005;95:3-8), (Sainte-Laudy J, Belon P. Use of four different flow cytometric protocols for the analysis of human basophil activation. Application to the study of the biological activity of high dilutions of histamine. *Inflamm. Res.* 2006;55:S23-S24).

C/ Since the fifties, research on high dilutions exists; quality and number of publications increased the last decennium. Critical studies and meta-analyses were done but were often denied or even ignored (see *COST B4 supplement report EUR 19110 ISBN 92-828-7434-6*). This research was never supported or even advised by the academic authorities.

Describing the most important surveys published in international journals, Professor Jean Cambar, dean of the faculty of pharmacy of Bordeaux, confirms the effects of high diluted homeopathic preparations. As example he quoted: The efficacy of very high dilutions of human and animal natural molecules (also called *endogenous molecules*), this was published several times in peer reviewed journals: Int J Immunotherapy 1987;3:191-200 (Thymulin in mice, Bastide M.), Int J Immunopharm 1990;6:211-214 (α/β interferon, Carriere V.), J Vet & Human Toxicol 1995:37(3):259-260/ Homeopathy 2008;97:3-9 (Thyroxine, Endler PC₂), Int J Immunopathol and Pharmacol 1996;9:43-51 (Bursin, Youbicier-Simo BL₂). The efficacy of very high dilutions, using pharmacological models, is published also in peer reviewed journals: Pathophysiol Haemost Thromb 2005;34:29-34 (Platelet aggregation in portal hypertension and its modification by ultra-low doses of aspirin, Eizavaga FX); Thrombosis res 2000;100:317-323 (Time related neutralization of two doses acetyl salicylic acid, Aguejouf O.); Thrombosis res 1998;90:215-221 (Combination of two doses of acetyl salicylic acid: experimental study of arterial thrombosis, Belougne-Malfatti E.); Thrombosis res 2000;99:595-602 (Effects of acetyl salicylic acid therapy on an experimental thrombosis induced by laser beam, Aguejouf O.); Thrombosis res 1998;89:123-127 (Thromboembolic complications several days after a single-dose administration of aspirin, Aguejouf O.); Thrombosis Res 1994;76:225-229 (Acetyl salicylic acid in a vessel model, Doutremepuich C.); Haemostasis 1993;23:8-12 (Effect af aspirin on embolization in an arterial model of laser-induced thrombus formation, Vesvres M.H.); Thrombosis res 1992;65:33-43 (In vitro platelets/endothelial cells interactions in presence of acetylsalicylic acid at various dosages, Lalanne M.C.); Haemostasis 1990;20:99-105 (Acetyl salicylic acid in healthy volunteers, Doutremepuich C.); Thrombosis Res 1987;48:501-504 (Acetylsalicylic acid in healthy volunteers,

Doutremepuich C). The oldest used model, the subject of several international publications is the <u>toxicologic</u> model (Arsenic, Phosphorus, Mercury, Cadmium, Cisplatina, Glutamate, Sulphate, Copper sulphate, etc...). It can be applied on plant and animal material, on cell cultures and even in clinical studies. This model is still used and is even the subject of cooperation between the Universities of Bern and Bologna, testing homeopathic treatments prepared from arsenic trioxide on plants. The germination of seeds and the length of the stems on the 7th day, are the analyzed variables. This group, under leading of Dr Lucietta Betti, department DISTA of agro-environmental Science and Technology, University of Bologna, published 6 recent experiments.

A systematic review of the in vitro evidence of high homeopathic potencies was published in 2007 (88). The conclusions are that even experiments with a high methodological standard could demonstrate an effect of high potencies. No positive result was stable enough to be reproduced by all investigators. Among those that have been replicated by independent investigators the action of mercuric bichloride on hydrolases and especially the action of histamine of the Anti-IgE triggered basophile granulocyte degranulation seemed to be the best reproducible (see above).

These experiments are conducted in controlled circumstances, with a sufficient amount of plants, animals or cells and with a statistically valid treatment. <u>These facts are indisputable</u>, statistically significant <u>and</u>, for some, reproducible, even if it is not possible to explain the obtained results with the molecular paradigm.

To explain these irrefutable facts, another scientific paradigm is needed. For many years another scientific paradigm exists, the paradigm of *body signifiers* (89). As such a scientific frame exists and the nature of the homeopathic medicine begins to be understood and even identified (90-91-92).

⁽⁸⁸⁾ Witt CM et al. The in vitro evidence for an effect of high homeopathic potencies – A systematic review of the literature. *Complement Ther Med*.2007;YCTIM-886:11 pages.

⁽⁸⁹⁾ Bastide M. et Lagache A, Revue Intern. Systémique, 1995;9:237-249 and Altern Ther Health Med. 1997;3:35-9.

⁽⁹⁰⁾ Rey L. Thermoluminescence of ultra-high dilutions of lithium chloride and sodium chloride. *Physica* 2003; A323: 67-74 / L.R. Rey, Low temperature thermoluminescence, *Nature* 391 (1988) 418 / L.R. Rey, Thermoluminescence de la glace, *C.R. Physique* 1 (2000) 107–110.

⁽⁹¹⁾ Rey L. Can low-temperature thermoluminescence cast light on the nature of ultra-high dilutions? *Homeopathy*. 2007;96:170-174.

⁽⁹²⁾ Rao ML, Roy R, Bell IR. The defining role of structure (including epitaxy) in the plausibility of homeopathy. *Homeopathy*. 2007;96:175-182.

Several audits of these publications are available and justify a **level of evidence I** (88-96-97). 75 publications were evaluated by a German team, 105 articles were analysed in a second audit examining the protecting effect against toxic substances (isopathic model). 70% of these publications are of unquestionable quality and show the positive effect of the homeopathic medicines used. In a third audit, 76 of the 162 analysed studies were classified as "best quality", the effects are meaningful and reproducible.

Other examples, new results since 2005:

- (93) Alecu & al. Effect of the homeopathic remedy Arnica Montana 7CH on mechanical trauma in mice. *Cultura Homeopathica*. 2007;20:16-18.
- (94) Alecu & al. Effect of the homeopathic remedies Arnica Montana and Staphysagria on the time of healing of surgical wounds. *Cultura Homeopathica*. 2007;20:19-21.
- (95) Dos Santos AL, Perazzo FF, Cardoso LGV, Carvalho JCT. In vivo study of the anti-inflammatory effect of Rhus Toxicodendron. *Homeopathy*. 2007;96:95-101.

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Costa BGB, Siqueira CM, Barbosa GM, Portela MB, Soares RMA, Holandino C. Development of a new biotherapic of Candida Albicans to the treatment of oral candidiasis using yeast cells cultures, placebo and Nystatin® controlled design./

Siqueira CM, Costa B, Amorim AM, Conzalvez M, Veiga VF, Lyrio C, Couceiro JN, Holandino C. Looking for a new biotherapic prepared from infectious influenza virus: an in vitro study. Virus H3N2, MDCK cells cultures, antiviral activity.

⁽⁹⁶⁾ Linde K, Jonas WB, Worke DMF, Wagner H, Eifel F. Critical review and meta-analysis of serial agitated dilutions in experimental toxicology. *Human Exp Toxicol* 1994;13:481-492.

⁽⁹⁷⁾ COST (Co-operation in Science and Technology) is a framework for scientific and technical co-operation, allowing co-ordination of nationally funded research on a European Union level. COST-B4 relates especially to co-operation of research activities on the medical, cultural, psychological, legislative and economic aspects on non-conventional medicine. Supplement of report 1999 EUR 19110 ISBN 92-828-7434-6.

CHAPTER VIII

Homeopathy in veterinary practice

The advantages of the analysis of results in veterinary practice are various. The environment where animals are living can be considered as stable and very similar for all the animals considered. Studies on large animal cohorts are easier to realise than for human. A double-blind design is easier to be obtained.

Of course the number of surveys is still few, but for two diagnoses, sufficient studies are published and reproduced; a "level of evidence I" could be obtained very soon.

These two considered diagnoses are infertility in cows (98-99-100) and mastitis in cows (101-102). These two problems have important consequences for public health; antibiotics (normally prescribed for mastitis) can be found, as residues, in the food chain. Therefore, the milk produced must be destroyed; the economic consequences for the sector are very important. Moreover, homeopathic treatment is the only one authorized by the European authorities in the framework of biological breeding.

Other results are coming from another farming activity: chickens are very sensitive to stress, when stressed, they are picking each other resulting in important losses in the production (103). The same happens for turkeys, they are very sensitive to haematomas caused by shocks during transportation. This problem can be reduced with 30% with homeopathic treatment. The problem of regulation of sexual hormones of sows in farms (104) is important for the farmer and for the cost in pig production; homeopathy can offer a solution without "ethical" problem or risks for the consumers.

This type of research will be extended in the coming years.

- (98) Aslan S, Findik M, Kalender H, Celebi M, Izkür H, Handler J (2000). Verbesserung der postpartalen Fertilität von Kühen durch Pulsatilla miniplex (Improvement of cows by Pulsatilla miniplex). *Wiener Tierärztliche Monatsschrift* 87:359-362.
- (99) Sekular PS, Dakshinder NP, Sarode DB, Rode AM, Kothedar MD (2000). Evaluation of homeopathic drugs in hypogalactia of cows. *Indian Veterinary Journal* 77:813-814.
- (100) Williamson AV, Mackie WL, Crawford WJ, Rennie B (1991). A study using Sepia 200c given prophylactically postpartum to prevent anoestrus problems in dairy cows. *British Homeopathic Journal*, 80:149-156.
- (101) Searcy R, Reyes O, Guajardo G (1995). Control of subclinical bovine mastitis. Utilization of a homeopathic combination. *British Homeopathic Journal* 84:67-70.
- (102) Varshney JP, Naresh R (2005). Comparative efficacy of homeopathic and allopathic systems of medicine in the management of clinical mastitis of Indian dairy cows. *Homeopathy*, **94**:81-85.
- (103) Filliat C. Particularité de l'utilisation de l'homéopathie en production avicole. *Annals of the "Entretiens Internationaux de Monaco 2002"*, 5-6 October 2002. http://www.giriweb.com.
- (104) Riaucourt A. L'Exemple de la Filière Porcine. *Annals of the "Entretiens Internationaux de Monaco 2002"*, 5-6 October, 2002. http://www.giriweb.com.

Examples of recent (2006-2008) veterinary homeopathic publications:

- (105) Chaudhuri S, Varshney JP. Clinical management of babesiosis in dogs with homeopathic Crotalus horridus 200C versus allopathy. *Homeopathy*. 2007;96:90-94.
- (106) Varshney JP. Clinical management of idiopathic epilepsy in dogs with homeopathic Belladonna 200 C: A case series. *Homeopathy*. 2007;46-48.
- (107) Lira-Salazar G, Marines-Montiel E, Torres-Monzon J, Hernandez-Hernandez F, Salas-Benito JS. Effects of homeopathic medications Eupatorium perfoliatum and Arsenicum album on parasitemia of Plasmodium berghei-infected mice (Malaria). *Homeopathy*. 2006;95:223-228.
- (108) Rajkumar R, Srivastava SK, Yadav MC, Varshney VP, Varshney JP, Kumar H. Effect of a Homeopathic complex on oestrus induction and hormonal profile in anoestrus cows. *Homeopathy*. 2006;95:131-135.
- (109) Berchieri A, Turco WCP, Paiva JB, Oliviera GH, Sterzo EV. Evaluation of isopathic treatment of Salmonella enteritidis in poultry. *Homeopathy*. 2006;95:94-97.

Aboutboul R. Snake remedies and eosinophilic granuloma complex in cats. *Homeopathy*. 2006;95:15-19.

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Magnani P, Conforti A, Bellavite P. Effects of homeopathic drugs on the anxiety-like behaviour in mice. Blind design, Diazepam and placebo controlled./

Boujedaini N. Action de Gelsemium sempervirens sur la synthèse d'allopregnanolone. Blind design versus placebo./

Castilhos. Effect of the Arnica Montana 200CH followed by Medicago Sativa 6CH and Calcarea Phosphorica 6CH usage in the feed consumption and weight gains of goat weaned kids. Double-blind placebo controlled trial./

Weber S, Endler PC, Welles SV, Suanjak-Traidl E, Scherer-Pongratz W, Frass M, Spranger H, Peithner G, Lothaller H. Thyroxine 30X, Electromagnetic field influence (microwave, mobile phone, x-ray) and highland frogs. Multi-centric, blinded controlled study on 2980 animals./

Payen L. The effect of the homeopathic drug PVB® Phytolac in mastitis of cows. Preventive double-blind design on 187 cows./

Issautier. Prevention of cold-intolerance in Guinea Fowl by homeopathic treatment and analysis of its effects. Single-blind study on 10.640 animals, homeopathy versus allopathy./

Peychev L. Changes in rat's learning and memory after a long treatment with four homeopathic medicines. Placebo-controlled study on 130 animals./

Sommer MA, Blaha T. Epidemiological investigations on the use of homeopathic remedies in swine under special consideration of the comparison of homeopathic and antimicrobial therapies. Open study including 36 sows./

Zalla Neto R, Bonamin LV. Lymphoid response and granuloma development in mice inoculated with BCG and treated with Thymulin in homeopathic preparations.

CHAPTER IX

Questioning homeopathic medicines

Considering the individualized patient's approach of Homeopathy, the scientific framework is much broader than could be expected. Homeopathic M.D. are mostly focused on research about individualization, similarity and globality. It does not exclude research on some diagnoses and a lot of indications are reaching a **IIIb level of evidence** and would be further considered for more research.

Examples from the 63rd LMHI congress on Evidence Based Homeopathy (2008):

Allergology:

Flitchev S, Nestorov I, Groudev D, Ivanov M. Les possibilities de l'homéopathie dans la prevention et dans le traitement de **l'asthme** chez des enfants atopiques. Etude prospective incluant 64 enfants.

Jurj G. Homeopathic treatment of **atopic dermatitis** in children. Prospective study on 35 patients.

Kekata M, Villano G, Ben Salah-Mezghanni S, Pellegrini A, Hayouni A, Mtiraoui A. **Asthme allergique** et thérapeutique homéopathique. Prospective study on 6 patients.

Macri F. Medical audit of paediatric patients with **allergic disorders**. Comparison study of two groups, 52 patients treated with allopathy, 50 patients treated with homeopathy.

Marijnen P, Fayard AL. Hypericum perfoliatum et **Lucite estival**e bénigne: de l'observation vétérinaire à l'indication thérapeutique. Preventive, prospective, multicentric study on 105 patients.

Popowski P. **Dermatite atopique** et recherche clinique en médicine ambulatoire. Retrospective study on 27 patients.

Vander Brempt X, Cumps J, Capieaux E. Efficacité clinique de 2LALERG dans le **rhume des foins**. Double-blind placebo controlled study on 41 patients.

Dentistry:

Camacho C, Lozano S, Melo M, Pedraza C, Vanegas S, Benitez G, Palencia R, Revelo I. Effectiveness of homeopathic medicine Arnica 7CH versus Naproxen® on **post operative extraction of third molar** including pain relief (15 patients).

Clercq JM, Capieaux E, Jenaer M. Micro-immunotherapy applied to **paradontal diseases**. Follow-up of 20 patients.

Jussara Diffini SM. **Oral health** of 6 to 14 year-old children treated with allopathy and homeopathy. Comparison study on 599 children.

Jussara Diffini S.M. Evaluation and comparison of **salivary conditions** of children with respiratory problems treated with allopathic and homeopathic medications. Comparison study on 90 patients.

Tiba H, Contin I, Itagaki C, Wierzchon LM, Fachada AP, Feighelstein GM. Application of the homeopathy in patients of TMD (**Temporo Mandibular Disorders**) and Orofacial Pain. Follow-up of 50 patients.

Gynecology:

Berrebi A, Parant O, Ferval F, Thene M, Ayoubi JM, Connan L, Belon P. Traitement de la douleur de la **montée laiteuse**, non-souhaitée, par homéopathie dans le post-partum immédiat. *J. Gynecol Obstet Biol Reprod* 2001 ;30 :353-557.

Chiche JL. Actea Racemosa 30CH dans la **dystocie cervicale** pendant l'accouchement. Etude sur 24 parturiantes.

Dungler T, Colas A. Sanguinaria Canadensis 7CH in the treatment of **flushes**. Study including 87 patients.

Honneger F, Lavallee V, Aguerre C, Cresp C, Desmonty-Minjon ML, Doussin-Dirks A, Ducos-Klingebiel S, Leblanc-Lebarazer A. **Mycoses vaginales récidivantes** et traitement homéopathique: un travail prospectif sur 13 patients.

Masson JL, Colas A. Prise en charge homéopathique des **bouffées de chaleur chez la femme ménopausée.** Prospective, multi-centric study on 438 patients. *Homeopathy* 2008;97(1):10-15.

Roca M. Treatment of **Prolactinoma** with homeopathy. Follow-up of 16 patients.

Shangloo GK. Evidence Based Medicine – Homeopathic cure to **uterine fibroid and ovarian cyst**. Follow-up of 123 patients.

Shukla P. Evidence Based Study on **breast lumps** and homeopathic management. Follow-up of 480 patients.

Hormonology:

Grelle L.C.E. Homeopathic treatment of subclinical **hypothyroidism**. Prospective follow-up of 5 patients.

Baroli A. Micro-immunotherapy applied to auto immune thyroid pathologies: clinical cases of **chronic thyroïditis**. Follow-up of two patients.

Infectiology:

Arjoun H, Demonceaux A, Monastiri K. Les **bronchiolites du nourrisson** et l'homéopathie. Etude comparative allopathie-homéopathie sur 40 cas.

Bahloul H, Musial E, Mahfoudh A. Traitement homéopathique de la **varicelle** de l'enfant. Etude comparative de l'évolution de 16 enfants et la littérature.

Derbel, Belkadhi M, Villamo G, Mtiraoui A. **Rhinopharyngites** à répétition chez l'enfant, prise en charge en homéopathie. Etude prospective de 25 cas.

Fayard AL. Traitement de **l'irritation oculaire** par un collyre homéopathique associant Euphrasia, Calendula et Magnesia Carbonica (Homeoptic®). Placebo controlled study on 31 patients.

Rusev DS, Petrova G. Sulfur iodatum – Subsidiary homeopathic medicine on **infectious diseases** of children. Follow-up of 24 children with long lasting fever of unknown origine.

Neurology:

Adler UC, Paiva NMP, Cesar AT, Adler MS, Molina A, Padula AE, Calil HM. Individualized homeopathic medicines versus fluoxetine for the acute treatment of adults with **depression**: double-blind randomized non inferiority trial on 59 patients.

Bolognani F, Mendes F, Kede J, Mendes P. Homeopathy and **muscular dystrophy** (Duchene, Becker, Limb Girdle, Steiner). Study on 242 patients.

Bolognani F, Mendes M, Mendes A, Kede J, Maia A. Relation between plumbum metallicum and **Progressive Spinal Amiotrophy** in Brasil. Study on 44 patients.

Bolognani F, Mendes D, Martins S, Maia A, Serpa C, Damasceno A, Fonseca G, Teixeira M, Durao F. **Attention Deficit Hyperactivity Disorder** in relation with Zincum metallicum. Study on 33 patients.

Damaceno AMG. Bolognani F, Xavier MF, Mendes AP, Serpa C. Homeopathic therapy on a study of **Infantile Cerebral Palsy**. 9 years follow-up of 275 patients.

Fonseca GR, Bolognani F, Durao F, Souza K, Acioly M, Bagarollo M. Study of homeopathic medication effects on cognitive and motor performance in **autistic children**. Follow-up of 7 children with a comparison group of 23 children.

Kivellos S, Papatriantafyllou J, Papilas K, Karagerogiou K, Vithoulkas G. Practicing classical homeopathy in a headache clinic of a major public hospital in Athens, Greece. Four years experience treating **migraine** patients. Follow-up of 36 patients.

Maia AP, Bolognani F, Mendes F, Fonseca G. The effect of homeopathic treatment in controlling **aggressiveness** in patients with cerebral palsy. 9 years follow-up in 57 patients.

Martins S, Bolognani F, Maia AP, Fraga CS, Mendes M. **Choreo Athetosis** condition and homeopathy. Follow-up of 75 patients.

Mateescu RA. **Attention Deficit Hyperactivity Disorder** in children and homeopathic treatment. Follow-up of 15 children.

Mendes MFX, Carillo Jr R, Gosik MS, Bolognani FA. **Parkinson's disease** and homeopathic therapy (serotoninum). Follow-up of 4 patients.

Naghiu NR. Homeopathic treatment and family input in treatment of **autism**. Prospective study on 118 patients.

Serpa C, Bolognani F, Martins S, Mendes F, Maia AP, Fonseca G. Influence of homeopathic drug on **cognition** of patients with cerebral palsy. Follow-up of 275 patients.

Teixeira MIM, Bolognani F. **Spastic condition** and Homeopathy. Retrospective study on 54 patients.

Roberfroid M, Cumps J, Henry MF, Jenaer M. Micro-immunothérapie et traitement de la sclérose en plaque: résultats d'une évaluation clinique de 59 patients.

Oncology:

Pevenage S. Expériences pratiques vétérinaires en oncologie en utilisant 2LC1 en association avec les traitements conventionnels. Follow-up de 15 cas.

Pharmacology:

Goyens M. Rules of Good Practice in Pharmacy.

Hendrickx J. Internal Quality Standards and Methods for Homeopathic Medicinal Preparations in Pharmacies.

Mouyart MA. A list of first safe dilutions, a tool for all.

Sollie P. Availability and accessibility of raw materials and stocks. Problems in the daily pharmaceutical practice.

Traumatology - Toxicology:

Khuda-Bukhsh A.R. Can homeopathy ameliorate sufferings of **arsenic victims**? A simplistic approach in management of a menacing rural health problem in India (contamined ground water). Placebo-controlled double-blind study on 225 patients.

Dobrev K. La place de l'homéopathie dans la préparation **préanesthésique et dans la période postopératoire** précoce dans département d'anesthésiologie et de soins intensifs de l'Hôpital Universitaire de Stara Zagora en Bulgarie.

Jansen JP, Bol JGB, Andringa HH. Use of homeopathy in the treatment of **post-traumatic stress disorder**. Review of results in three homeopathic practices in Gröningen. Retrospective study of 23 patients.

This list is not exhaustive. A lot of cases series are regularly published in all area of medicine. Topics are various and linked to the main questions in medicine. The risk for a pandemic influenza is a real concern of medicine at this time, you could see in chapter VII that homeopathic basic research on this topic is already published and on going, clinical studies are ready to start (preventive and curative).

CHAPTER X

Conclusions

- Homeopathy is mostly used in medicine in the framework of general practice (but also by gynaecologists, paediatricians, etc) and is used by patients of all ages.
- The respect for patients' rights means that the patient must be informed about all possible therapies that could be used to improve his/her health and also about the therapeutic possibilities of homeopathic medicines even when in hospital.
- The absence of a correct medical diagnosis at the start of a treatment is currently the only possible risk when using homeopathy as treatment. That is why it is necessary that medical doctors are dedicated to the practice of homeopathy.
- **♣** The **level of evidence** obtained for numerous diagnoses is sufficient to accredit homeopathic practice in the scientific framework of the general practice.
- ♣ The use of homeopathy in general practice may imply a reduction in costs for public health. These savings are coming from a reduction of prescribed conventional remedies, a reduction in the number of consultations and a reduction in the number of days absent from work
- 4 The number of competent homeopathic physicians is not sufficient to cover the demand of the population. Therefore it is important to promote information sessions and education into homeopathy in the framework of the general practice.
- → University research on homeopathy must be encouraged, stimulated and supported by the public health authorities.
- ♣ Basic research results and veterinary research results are confirming the obtained results by humans. This is a specific effect supported by a new scientific paradigm.
- ♣ The internal evidence is validating and confirming the effects of the medical homeopathic method.

The facts proposed in this report are indisputable. Homeopathy must be accepted in the scientific framework of medicine, especially in the general medical practice frame. Research must be supported and amplified. Objective information is needed for patients. Education in homeopathy encouraged in the frame of medicine.

Το ηλεκτρονικό αυτό έντυπο παρέχεται από την

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